

MAR 24 2011

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Navitrack[®] System – OS Knee Universal

Applicant: Zimmer CAS
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Contact Person: Christopher McLean

Date Summary Prepared: January 6, 2011 (revised February 18, 2011)

Device Trade Name: Navitrack[®] System – OS Knee Universal

Device Classification Name: Orthopedic Stereotaxic Instrument (OLO); 21 CFR § 882.4560

Predicate Device:

Navitrack[®] System – OS Knee Universal; from Orthosoft Inc. (name changed to Zimmer CAS); 510(k) # K060336

Device Description:

The Navitrack[®] System – OS Knee Universal device consists of software, a computer workstation, an optical tracking system, surgical instruments, and tracking accessories, designed to assist the surgeon in the placement of total knee replacement components. Tracking devices are incorporated with given surgical instruments, as well as on to fixation bases that attach to each of the femur and tibia, such to allow the ability to track and display to the user their respective positions intra-operatively. The femur and tibia are displayed to the user in the form of their main alignment axes. The alignment axes are determined and recorded intra-operatively by identifying the key anatomical references that are used clinically to align and position the components.

Indications for Use / Intended Use:

The Navitrack[®] System – OS Knee Universal is indicated for use as a stereotaxic instrument to assist in the positioning of Total Knee Replacement components intra-operatively.

It is a computer controlled image-guidance system equipped with a three-dimensional tracking sub-system. It is intended to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, and in precisely positioning the alignment instruments relative to these axes by displaying their locations.

Technological Comparisons to the Predicate:

The fundamental scientific technology of the predicate is unchanged including the operating principle and control mechanism. The changes involved adding two new instruments to the system: the Same Incision Tibia Reference and the Same Incision Femoral Reference. They are modified versions of the bone references already included in the predicate without any change to their intended use to allow tracking the tibia and femur. The bone attachment base of the references in the predicate were modified to allow their attachment respectively to the edges of the distal femur and the top of proximal tibia as opposed to the areas closer to or on the main bone shafts per the predicate version.

The remaining portions of the references were unchanged such that the references will be tracked identically as the predicate ones. However, given that they are to be attached in areas which are resected as part of the TKR bone cuts, the references are to be removed once the cutting blocks have been navigated. This limits the permissible navigation functionalities to the primary distal femoral and proximal tibial cuts.

In addition the notification included the updated information of other changes that have been incorporated in the predicate since the original notification. These involved secondary engineering changes and improvements (ergonomics of patient-user interface, dimensional specifications, software changes). They did not involve changes to the intended and indication for use and did not raise any new issues of safety and effectiveness. These included the following: a more recent model for the tracking system and related software modifications to replace the obsolete previous version, a collapsible frame for the workstation to facilitate packaging and shipping, offset versions for the bone reference to allow offsetting their attachment to the subject bones, a Posterior/Distal Condyle Digitizer and related software modifications to combine the femoral distal and posterior digitization functions, a Femoral Cut Alignment Guide along with attachment and cutting guide accessories as an alternate manual alignment guide to the alignment guides of standard instrumentation systems, a Adjustable Spacer with Drill Guides and adjustment accessories to help the surgeon manually adjust the condylar gaps and correspondingly position the implant components, a Natural-Knee II Saw Capture to modify the saw slot capture of the cutting guide of the Natural Knee II (Zimmer Inc. USA) to facilitate its use with the system, software modifications to allow navigating the A/P placement and rotation of given implant femoral components for an anterior cut first sequence, software modifications to allow navigating anterior cutting plane guides, modifications to allow digitizing landmarks on the medial and lateral edges of the femoral condyles and estimate the femoral medial size component, modifications to provide an alternate axis for the tibial coordinate system, addition of automatic transitions between sequential steps, modifications to the acceptance threshold parameters of the femoral head center functionality to improve its performance, and user interface updates per the above changes.

Performance Data:

Non-clinical tests were performed to assess that no new safety and efficacy issues were raised in the device. These included tests and analyses to verify that the proposed bone references function as required within the system, that they provide adequate fixation characteristics, and that they do not present interference issues with other instrumentation components. Validation tests were performed per simulated use on cadavers.

For the other changes, non-clinical verification and validation test including bench tests and simulated use on cadaver specimens were also performed to assess that no new safety and efficacy issues were raised.

Conclusion:

The information and data provided in this 510(k) Premarket Notification established that the Navitrack® System – OS Knee Universal Knee device is substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room -WO66-G609
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MAR 24 2011

Re: K110054

Trade/Device Name: Navitrack® System – OS Knee Universal

Regulation Number: 21 CFR 882.4560

Regulation Name: Stereotaxic instrument

Regulatory Class: Class II

Product Code: OLO

Dated: February 18, 2011

Received: February 22, 2011

Dear Mr. McLean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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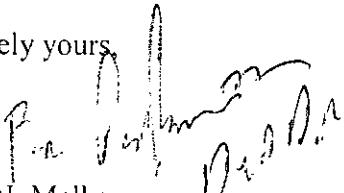
or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K110054

Device Name: Navitrack® System - OS Knee Universal

Indications for Use:

The Navitrack® System – OS Knee Universal is indicated for use as a stereotaxic instrument to assist in the positioning of Total Knee Replacement components intra-operatively.

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Prescription Use
(per 21CFR 801.109)

OR

Over-the-Counter Use _____

Concurrence of CDRH Office of Device Evaluation (ODE)

Neil R. Bergman for ODE
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110054